

# 해외 의약품 인허가 현황 (2020.8.10.~2020.8.16.)

한국바이오의약품협회, 2020.8.18.

## ○ 미국 2건 (출처: FDA)

Approval date	Drug name	Active Ingredients	Submission Classification	Company	비고
08/12/2020	VILTEPSO NDA #212154	VILTOLARSEN	신물질	NIPPON SHINYAKU CO LTD	
08/14/2020	ENSPRYNG BLA #761149	SATRALIZUMAB		GENENTECH	바이오의약품

## ○ 유럽 2건 (출처: EMA)

Approval date	Drug name	Active Ingredients	Therapeutic area	Marketing-authorisation holder	비고
31/07/2020	Pretomanid FGK	Pretomanid	Tuberculosis, Multidrug-Resistant	FGK Representative Service GmbH	
31/07/2020	Hepcludex	Bulevirtide acetate	Hepatitis D, Chronic	MYR GmbH	